EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY) - Registration

Primary Reviewer's Name/Title: Chris Peterson, Toxicologist

STUDY TYPE:	PRODUCT PERFORMANCE: OCSPP 810.3300
MRID:	437228-09; The Evaluation of the Efficacy of Q-Sect IGR Flea Collar for Cat Flea Control on Dogs, Cruthers, L.R., 1995.
DP BARCODE:	430469
DECISION NO:	507781
SUBMISSION NO:	972241
SPONSOR:	Daniel T. Ruth, Manager Regulatory Affairs
TESTING FACILITY:	Professional Laboratory and Research Services, Inc., Route 1 Box 3AA, Corapeake, NC 27926
STUDY DIRECTOR or INVESTIGATOR:	Larry R. Cruthers, Study Director
SUBMITTER:	Daniel T. Ruth, Manager Regulatory Affairs
STUDY COMPLETED:	17/06/1994
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	This study was conducted in compliance with 40 CFR 160 Federal regulations for "Good Laboratory Practice."
TEST MATERIAL:	PRODUCT NAME: SPCP4 Plus 1 EPA REGISTRATION NUMBER OR FILE SYMBOL: 2517-RTT ACTIVE INGREDIENT NAME: Deltamethrin, Pyriproxyfen CHEMICAL NAME: Not provided PC CODE: PRIA CAS NO.: Not provided FORMULATION TYPE: Dog Collar PRODUCT APPLICATION RATE(S): Deltamethrin 4.00%, Pyriproxyfen 1.00%

ACTIVE INGREDIENT APPLICATION RATE(S): 1 collar per dog, small dog: 736 mg/dog Deltamethrin + 184 mg/dog Pyriproxyfen, medium dog: 964 mg/dog Deltamethrin + 241 mg/dog Pyriproxyfen, large dog: 1100 mg/dog Deltamethrin + 275 mg/dog Pyriproxyfen

Efficacy Study Data Evaluation Record

Title: The Evaluation of the Efficacy of Q-Sect IGR Flea Collar for Cat Flea Control on Dogs

Purpose/Objective:

The objective of this study was to evaluate the efficacy of an experimental 3M collar containing nylar for reproduction inhibition of the cat flea on dogs.

The justification for this test system was that dogs are one of the target systems for the commercial product. The route of administration was chosen by the sponsor.

Materials and Methods

Test Material(s):

Group A- 3M Nylar Collar
Lot No. 93709113 A2, A3, A4, A6, A7, A8

Group B- 3M Nylar Collar
Lot No. 93709113 B1, B2, B3, B5, B7, B10

Each collar had a mean initial mass of 12.15 g, which declined to 3.15 g after one year, losing a mean of 9.0 g. The active ingredient concentrations were not provided, and the results of a nylar depletion study that might have provided this information are referenced to Appendix 1, which was not provided.

Test Location: Corapeake, NC

Positive Control/Reference Standard, if used: Not used

Species Tested:

- Common name and scientific name of each species. Cat flea, *Ctenocephalides felis*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Unfed adult
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. PLRS in-house colony
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not described

Experiment description:

- List the treatments including the untreated control.

Group A- 3M Nylar Collar
Lot No. 93709113 A2, A3, A4, A6, A7, A8

Group B- 3M Nylar Collar
Lot No. 93709113 B1, B2, B3, B5, B7, B10

Each collar had a mean initial mass of 12.15 g, which declined to 3.15 g after one year, losing a mean of 9.0 g. The active ingredient concentrations were not provided, and the results of a nylar depletion study that might have provided this information are referenced to Appendix 1, which was not provided

Untreated replicate consisted of 6 dogs treated as were the test animals but not wearing the test collar.

- Include a description of:
  - Test arenas and/or apparatus (include site description and location):

On Test Days 0, 7, 14, 21, 28, 35, 42 and 49, each dog was infested with approximately 100-200 unfed adult fleas.

The ovicidal portion of this study was extended as follows: The dogs in all three test Groups were infested with fleas, as previously described on Test Days 63, 77, 91, 105, 119, 133, 147, 161, 175, 189, 202, 217, 230, 263, 273, 286, 301, 312, 329, 350 and 363. Ova were collected from each of the dogs on the fourth day following each of these infestations, i.e. Test Days 67, 81, 95, 107, 123, 137, 151, 165, 179, 193, 206, 221, 234, 267, 277, 290, 305, 316, 333, 354 and 367. These ova were observed at ~72 hours and handled as previously described.

placed in the petri dish. Each petri dish was labeled with tape that indicated the dog number, study number, calendar date, etc.

The dishes were observed (counted) for larval hatch at approximately 72 hours post-collection. Flea growth medium was added to each dish after the larval hatch was determined. Adult flea counts of each dish were made at 21, 28 and 35 days post-collection. Each dog was washed with a non-insecticidal shampoo to remove existing flea populations.

- Method(s) of application: Treated collar
- Number of replicates per treatment: 6 dogs
- Number of individuals per replicate: 100 to 200 fleas at intervals throughout the study
- Length of exposure to treatment (time in seconds, minutes or hours): 4 days
- Were tested specimens transferred to clean containers? Yes
- Experimental conditions (state relative humidity, temperature, and photoperiod): Laboratory conditions, specifics not reported
- The type of harborage if used in the experiment: See test apparatus description above
- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move):

The dishes were observed (counted) for larval hatch at approximately 72 hours post-collection. Flea growth medium was

Product efficacy was determined at 35 days following each reinfestation using the following formula:

$$\text{Percent of adult fleas in the "control" dishes} - \frac{\text{Percent of adult fleas in "treated" dishes}}{\text{Percent of adult fleas in the "control" dishes}} \times 100$$

- Report if morbidity and mortality were recorded separately: NA; data based on number of ova collected and live larvae hatched
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

- 100% ovicidal effect was observed in both treatment groups from day 4 to 367 following periodic re-infestations four days after each re-infestation.

- Deviations or amendments from the protocol.

On Test Day 66, Dog # 5191 destroyed its second collar (Collar ID 9319-A-9) and was fitted with the only remaining Test Group A replacement collar (Collar ID 9319-A-10). Since this collar that had been hung up on Test Day -6 and not Test Day -7 (as per SOP), this can be considered a deviation from the protocol, since the SOP was referenced in the protocol. However, this deviation has no impact on the results of this study.

Other deviations are mentioned in the text, but are not described in detail

- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed.
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
  - Formulation type (e.g. aerosol, granular): Treated collar
  - Application type (e.g. direct, surface, area): Surface
  - Timepoints at which corresponding control mortality is greater than 10%: NA; data based on comparison of living flea hatch compared to control

Conclusions

- Use of one 3M Nylar collar per dog caused ≥90% ovicidal effect from day 4 to 367 of the test as determined by egg hatch 4 days after each periodic re-infestation.
- Sufficient eggs were collected, indicating a true ovicidal effect.
- The active ingredient concentrations were not provided, and the results of a nylar depletion study that might have provided this information are referenced to Appendix 1, which was not provided.
- Loss of collar mass could be due to washing or other activities, and the 9.0 g loss might not directly correlate to delivery of active ingredient to the dogs, as supported by the ambiguous results of the dog hair analysis reported in the MRID.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 441901-01; Deltamethrin Dog Collars—Efficacy Studies, Lauber, J.J., 1996 [This MRID contains 6 studies].

OCSPP Product Performance Guideline: 810.3300

Product Name: SPCP4 Plus 1
EPA Reg. No. or File Symbol: 2517-RTT
Decision number: 507781
DP number: 430469

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-296

Primary Reviewer:
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Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY) - Registration

Primary Reviewer's Name/Title: Chris Peterson, Toxicologist

STUDY TYPE:	PRODUCT PERFORMANCE: OCSPP 810.3300
MRID:	441901-01; Deltamethrin Dog Collars—Efficacy Studies, Lauber, J.J., 1996 [This MRID contains 6 studies].
DP BARCODE:	430469
DECISION NO:	507781
SUBMISSION NO:	972241
SPONSOR:	Roussel Bio Corporation, 170 Beaverbrook Rd., Lincoln Park, NJ
TESTING FACILITY:	Hoechst Roussel Vet, P.O. Box 2500, Somerville, NJ 08876-1258
STUDY DIRECTOR or INVESTIGATOR:	Not provided (individual studies might or might not have a study director named)
SUBMITTER:	John J. Lauber, Manager, Product Registration, Animal Health
STUDY COMPLETED:	19/08/1996
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	The submitted of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR 160.
TEST MATERIAL:	PRODUCT NAME: SPCP4 Plus 1 EPA REGISTRATION NUMBER OR FILE SYMBOL: 2517-RTT ACTIVE INGREDIENT NAME: Deltamethrin, Pyriproxyfen CHEMICAL NAME: Not provided PC CODE: PRIA CAS NO.: Not provided

FORMULATION TYPE: Dog Collar

PRODUCT APPLICATION RATE(S): Deltamethrin 4.00%, Pyriproxyfen 1.00%

ACTIVE INGREDIENT APPLICATION RATE(S): 1 collar per dog, small dog: 736 mg/dog Deltamethrin + 184 mg/dog Pyriproxyfen, medium dog: 964 mg/dog Deltamethrin + 241 mg/dog Pyriproxyfen, large dog: 1100 mg/dog Deltamethrin + 275 mg/dog Pyriproxyfen

Study 1

Efficacy Study Data Evaluation Record

Title: Final Report on the Evaluation of Deltamethrin Collars for Flea and Tick Control on Dogs (RBD 191)

Purpose/Objective:
Evaluate efficacy of two Deltamethrin collars for controlling fleas and ticks on dogs.

Materials and Methods

Test Material(s):
1. 3% Deltamethrin: DTM 3%, R91-182, Lot #1103
2. 4% Deltamethrin: DTM 4%, R91-183, Lot #1104

Market Standard: Escort Flea and Tick Collar, 15% Diazanon, Lot #0-GYR-02

Test Location: Greenbrier, AR

Positive Control/Reference Standard, if used: Escort flea collar, as described above

Species Tested:

- Common name and scientific name of each species. Flea, *Ctenocephalides* (species not identified); brown dog tick, *Rhipicephalus sanguineus*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Not reported
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not described

Experiment description:

- List the treatments including the untreated control.

1. 3% Deltamethrin: DTM 3%, R91-182, Lot #1103
2. 4% Deltamethrin: DTM 4%, R91-183, Lot #1104

Market Standard: Escort Flea and Tick Collar, 15% Diazanon, Lot #0-GYR-02

Application methods were not described
Untreated replicates were not described

- Include a description of:
  - Test arenas and/or apparatus (include site description and location): Not described
  - Method(s) of application: Treated collar
  - Number of replicates per treatment: Not reported
  - Number of individuals per replicate: Not reported
  - Length of exposure to treatment (time in seconds, minutes or hours): Not reported
  - Were tested specimens transferred to clean containers? Not reported
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported
  - The type of harborage if used in the experiment: Not reported
  - The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Not reported
  - Report if morbidity and mortality were recorded separately: Not reported
  - Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not reported

Data Reported/Results

Species	Treatment	Days ≥90% Efficacy Observed
Flea	3% Deltamethrin collar	21 to 77*, 105 to 182, 210, 294, 322, 406
	4% Deltamethrin collar	105 to 182*, 210 to 294, 322 to 434, 462
	Escort Collar	3, 7, 14, 21 to 77, 118 to 182, 210 to 294
Tick	3% Deltamethrin collar	7 to 77, 118, 147 to 434*
	4% Deltamethrin collar	7 to 77, 118, 147 to 434*
	Escort Collar	Not observed

* Data for these time points given as a range that included observations below 90%

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. 3% Deltamethrin collar: Flea: days 21 to 77*, 105 to 182, 210, 294, 322, 406; Tick: days 7 to 77, 118, 147 to 434*. 4% Deltamethrin collar: Flea: days 105 to 182*, 210 to 294, 322 to 434, 462; Tick: days 7 to 77, 118, 147 to 434*. Escort Collar: Flea: days 3, 7, 14, 21 to 77, 118 to 182, 210 to 294. *Intermittent control over 90%
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal

- Formulation type (e.g. aerosol, granular): Treated collar
- Application type (e.g. direct, surface, area): Surface
- Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Use of a 3% Deltamethrin collar caused ≥90% efficacy against flea on days 21 to 77 (intermittent), 105 to 182, 210, 294, 322, 406 and ticks on days 7 to 77, 118, 147 to 434 (intermittent).
- Use of a 4% Deltamethrin collar caused ≥90% efficacy against flea on days 105 to 182 (intermittent), 210 to 294, 322 to 434, 462 and ticks on days 7 to 77, 118, 147 to 434 (intermittent).
- Use of an Escort collar containing 15% Diazinon caused ≥90% efficacy against flea on days 3, 7, 14, 21 to 77, 118 to 182, 210 to 294.
- Data were presented in a way that prevented precise observations of 90% efficacy.
- Untreated control replicates not described or reported.
- Much of the treatment methods description is not included and affects the ability to review this study.

Study 2

Efficacy Study Data Evaluation Record

Title: Evaluation of the Flea and Tick Control Efficacy of a 3 and 4 Percent DTM Collar as Compared to the Market Standard (Escort®) when Applied to Dogs

Purpose/Objective:
Twenty-four (24) dogs of mixed breeding were used to compare the flea and tick control efficacy of 3% DTM, 4% DTM and Escort collars.

Materials and Methods

Test Material(s): DTM Collars, 3 and 4% DTM

Test Location: California

Positive Control/Reference Standard, if used: Escort® Collars

Species Tested:

- Common name and scientific name of each species. Flea (species not identified); brown dog tick, *Rhipicephalus sanguineus*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Not reported
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not reported

Experiment description:

- List the treatments including the untreated control. 3% DTM Collar, 4% DTM Collar, Escort Collar
- Include a description of:
  - Test arenas and/or apparatus (include site description and location):
    Periodically, the dogs were infested with 100 fleas and 50 Brown Dog ticks. Subsequently, the parasites were counted to evaluate the flea and tick control efficacy provided by the experimental collars.
  - Method(s) of application: Treated collar
  - Number of replicates per treatment: Not reported
  - Number of individuals per replicate: 24 dogs in total, how distributed among treatments was not described
  - Length of exposure to treatment (time in seconds, minutes or hours): 190 days
  - Were tested specimens transferred to clean containers? Not reported
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported

- The type of harborage if used in the experiment: Not reported
- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Not described
- Report if morbidity and mortality were recorded separately: Not reported
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

The 3 and 4% DTM collars gave superior flea and tick control to the Escort collar. The 4% DTM collar was superior to the 3% collar, and provided between 82.1 and 97.4% flea control and between 98.6 and 100.0% tick control for the duration of the 190-day study. The Escort collar gave very poor tick control.

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. Fleas: 190 days (intermittent), ticks: 190 days
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
  - Formulation type (e.g. aerosol, granular): Treated collar
  - Application type (e.g. direct, surface, area): Surface
  - Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Use of a 4% DTM collar caused ≥90% efficacy against fleas for 190 days (intermittent) and against ticks for 190 days.
- The manner the data were reported, as a range, prevented precise determination of ≥90% efficacy observations.
- Very few experimental details were provided.

Study 3

Efficacy Study Data Evaluation Record

Title: Evaluation of DTM Collars and Comparison to Market Standard against Fleas and Ticks

Purpose/Objective: Not stated

Materials and Methods

Test Material(s): 3% DTM Collar, 4% DTM Collar

Test Location: Stillwater, OK

Positive Control/Reference Standard, if used: Escort® Collar

Species Tested:

- Common name and scientific name of each species. Cat flea, *Ctenocephalides felis*; brown dog tick, *Rhipicephalus sanguineus*; American dog tick, *Dermacentor variabilis*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Not reported
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not reported

Experiment description:

- List the treatments including the untreated control. 3% DTM Collar, 4% DTM Collar, Escort Collar

Treatments included: (1) untreated control; (2) Dog collars-Experimental-DTM 4%; (3) Dog collars-Experimental-DTM 3%; and (4) Commercial product-Escort© (Schering Corp.) Efficacy and

- Include a description of:
  - Test arenas and/or apparatus (include site description and location):

Thirty-two beagle dogs were maintained within indoor runs and were divided into four treatment groups of 8 dogs each.

  - Method(s) of application: Treated collar
  - Number of replicates per treatment: 8
  - Number of individuals per replicate: 1 dog
  - Length of exposure to treatment (time in seconds, minutes or hours): Continuous
  - Were tested specimens transferred to clean containers? Not reported
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported

- The type of harborage if used in the experiment: Not reported
- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Not described
- Report if morbidity and mortality were recorded separately: Not reported
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

variablis) for ca 1 year. After a slow initial start, 4% DTM collars gave near complete flea control for days 30-378 and good to excellent control of brown dog ticks during the same period up to about 300 days. The 3% DTM collar was slightly less effective for about 300 days. The Escort® collar was not particularly effective at any time, but did give good flea control from Days 75-137. It was ineffective against ticks. The DTM 4% collar was also quite effective against the American dog tick up to day 300.

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. Not determinable
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
  - Formulation type (e.g. aerosol, granular): Treated collar
  - Application type (e.g. direct, surface, area): Surface
  - Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Because no data were reported, ≥90% efficacy levels could not be determined.
- Much of the important testing data and results are missing.

Study 4

Efficacy Study Data Evaluation Record

Title: The Efficacy of Three Different Types of Collar when Applied to Dogs against Infestations of Adult *Rhipicephalus sanguineus*

Purpose/Objective:

The objective of this study was to evaluate the efficacy of three different collars when applied to dogs against infestations of adult *Rhipicephalus sanguineus* on dogs.

Materials and Methods

Test Material(s):

Dogs assigned to Group 2 (n = 8) were fitted a single Roussel UCLAF Animal Health Collar (4% Deltamethrin) on Study Day 0.

Dogs assigned to Group 3 (n = 8) were fitted a single Bayer Collar (Kiltix®) on Study Day 0.

Dogs assigned to Group 4 (n = 8) were fitted a single Virbac Collar (Preventic®) on Study Day 0.

Active ingredients of Kiltix was not provided
Preventic contained an unreported concentration of Amitraz

Test Location: Mayo, Ireland. This study reports results on a species of interest in the United States

Positive Control/Reference Standard, if used: Kiltix and Preventic collars as described above

Species Tested:

- Common name and scientific name of each species. Brown dog tick, *Rhipicephalus sanguineus*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Adult, mixed sex
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not described

Experiment description:

- List the treatments including the untreated control.

  Dogs assigned to Group 2 (n = 8) were fitted a single Roussel UCLAF Animal Health Collar (4% Deltamethrin) on Study Day 0.

  Dogs assigned to Group 3 (n = 8) were fitted a single Bayer Collar (Kiltix®) on Study Day 0.

  Dogs assigned to Group 4 (n = 8) were fitted a single Virbac Collar (Preventic®) on Study Day 0.

Active ingredients of Kiltix was not provided
Preventic contained an unreported concentration of Amitraz
Untreated replicates are not described or reported

- Include a description of:
  - Test arenas and/or apparatus (include site description and location):

    Twenty five unfed adult *Rhipicephalus sanguineus* of mixed sex ratio (approximately 50:50) were applied to each dog on Study Day -2, Study Days 7, 14, 30, 60, 90, 120, 150, 180 and 210.

    Evaluation of the residual insecticidal activity of each collar was made by reinfesting dogs as outlined above and by carrying out tick counts on Study Days 8-10, 15-17, 31-33, 61-63, 91-93, 121-123, 151-153, 181-183, 211-213 respectively.

  - Method(s) of application: Treated collar
  - Number of replicates per treatment: 8
  - Number of individuals per replicate: 1 dog
  - Length of exposure to treatment (time in seconds, minutes or hours): 24, 48 and 72 hr after tick re-infestation
  - Were tested specimens transferred to clean containers? Not reported
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported
  - The type of harborage if used in the experiment: Not described
  - The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move):

    The initial knockdown mortality of each collar type against adult ticks was evaluated by carrying out tick counts at 24, 48 and 72 hours after treatment on Study Day 0.

  - Report if morbidity and mortality were recorded separately: Not recorded separately
  - Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

The % knockdown mortality was 15, 45 and 78 on Study Days 1 - 3 respectively for dogs fitted with Roussel UCLAF Animal Health Collar. The % knockdown mortality was 26, 92 and 100 on Study Days 1 - 3 respectively for dogs fitted with Kiltix® collar. The % knockdown mortality was 79, 87 and 98 % on Study Days 1 - 3 respectively for dogs fitted with Preventic® collar.

For the Roussel UCLAF and the Bayer Kiltix collars the residual mortality remained above approximately 80% for the entire study. The residual mortality for the Virbac Preventic Amitraz Collar remained above approximately 80% up to Study Day 153. On Study Day 181, the mortality declined to 47% but on days 182 and 183 it increased to 84 and 97% respectively. There was a significant decrease in residual mortality below 63% between Study Days 211 and 213 for the Virbac Preventic Amitraz Collar.

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
    - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. Initial infestation: Kiltix Collar: 2 and 3 days after infestation, Preventic Collar: 3 days. Re-infestations: Preventic Collar: day 183
    - Tested a.i. application rate: Not determinable
    - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
    - Formulation type (e.g. aerosol, granular): Treated collar
    - Application type (e.g. direct, surface, area): Surface
    - Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Use of a Kiltix collar caused ≥90% knockdown mortality to brown dog tick 2 and 3 days after initial infestation.
- Use of a Preventic collar caused ≥90% knockdown mortality to brown dog tick 3 days after initial infestation and on day 183 during periodic re-infestations.
- Precise 90% efficacy levels were not determinable based on the nature of the data reported.
- Important details about the testing methods were missing from this report.

Study 5

Efficacy Study Data Evaluation Record

Title: Evaluation of the Efficacy of Collars against Ticks on Naturally Infested Dogs

Purpose/Objective:

Aims: To evaluate the eradication power, residual activity and repellent effect of collars containing deltamethrin ("Scalibur") against ticks on naturally infested dogs.

Materials and Methods

Test Material(s): Scalibur collar, containing an unreported concentration of Deltamethrin

Test Location: Valenzano, Italy. This study reports results on a pest of relevance in the United States

Positive Control/Reference Standard, if used: Not used

Species Tested:

- Common name and scientific name of each species. Brown dog tick, *Rhipicephalus sanguineus*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Larvae and adults
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Natural populations in a dog kennel
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. NA; natural field populations used

Experiment description:

- List the treatments including the untreated control. Scalibur collar, containing an unreported concentration of Deltamethrin. 20 untreated control dogs are mentioned but not described.
- Include a description of:
  - Test arenas and/or apparatus (include site description and location): "heavily infested kennel"
  - Method(s) of application: Treated collar
  - Number of replicates per treatment: Not reported
  - Number of individuals per replicate: 1 dog
  - Length of exposure to treatment (time in seconds, minutes or hours): Continuous
  - Were tested specimens transferred to clean containers? No
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported
  - The type of harborage if used in the experiment: Not reported

- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Not described
- Report if morbidity and mortality were recorded separately: Not reported
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

The "Scalibur" collars containing deltamethrin, showed good eradication powers and provided complete protection against both larval and adult ticks (*Rhipicephalus sanguineus*) (no nymphs were found), in dogs living in a heavily infested kennel. This protection appeared after a period of between a minimum of 24 hours and a maximum of 10 - 20 days from the fitting of the collar and lasted up to the 90th day, beyond which no more ticks were found, even in the control dogs.

As a result it was impossible to assess residual activity up to the 180th day (6 months), as was demanded in the experimental protocol, since the life cycle of *Rhipicephalus sanguineus* (the only species present in the kennel) came to a halt.

However, it should be noted that during the re-infestations that occurred from the 60th day and which lasted until the 90th day, involving 15 untreated dogs out of 20 (i.e. 75%), none of the dogs wearing a collar was infested.

- Deviations or amendments from the protocol. Loss of tick populations in control dogs after 90 days
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. From the first to 10 or 20th day to 90 days
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
  - Formulation type (e.g. aerosol, granular): Treated collar
  - Application type (e.g. direct, surface, area): Surface
  - Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Use of a Scalibur collar containing an unreported concentration of Deltamethrin caused ≥90% reduction in tick numbers on dogs from between the first to 10 or 20th day to the 90th day.
- Because of how the data were presented, determination of 90% efficacy was not possible.
- Much of the important information in this study was not provided.

Study 6

Efficacy Study Data Evaluation Record

Title: Evaluation of the Efficacy of Collars against Fleas on Naturally Infested Dogs

Purpose/Objective:

Aims: To evaluate the eradication power, residual activity and repellent effect of collars containing deltamethrin ("Scalibur") against fleas on naturally infested dogs.

Materials and Methods

Test Material(s): Scalibur collar, containing an unreported concentration of Deltamethrin

Test Location: Valenzano, Italy. This study reports results on a pest of relevance in the United States

Positive Control/Reference Standard, if used: Not used

Species Tested:

- Common name and scientific name of each species. Cat flea, *Ctenocephalides felis*; dog flea, *Ctenocephalides canis*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Not reported
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Natural populations in a kennel
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. NA; natural field populations used

Experiment description:

- List the treatments including the untreated control. Scalibur collar, containing an unreported concentration of Deltamethrin. Untreated controls were not described or reported
- Include a description of:
  - Test arenas and/or apparatus (include site description and location): "Seriously infested kennel"
  - Method(s) of application: Treated collar
  - Number of replicates per treatment: Not reported
  - Number of individuals per replicate: 1 dog
  - Length of exposure to treatment (time in seconds, minutes or hours): Continuous
  - Were tested specimens transferred to clean containers? Not reported
  - Experimental conditions (state relative humidity, temperature, and photoperiod): Not reported
  - The type of harborage if used in the experiment: Not described

- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Not reported
- Report if morbidity and mortality were recorded separately: Not reported
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

The "Scalibor" collars containing deltamethrin, provided complete protection against fleas (*Ctenocephalides felis felis, Ctenocephalides canis*) on dogs living in a seriously infested kennel from the 6th day after fitting up until the 90th day. From the 90th day up until the end of the trial (195th day), protection was incomplete to the extent that it was lacking for brief periods of time (one positive examination) in three dogs, and for longer periods (4 and 7 examinations respectively) in two dogs, and completely lacking in one dog.

Because of the high parasite pressure that was a feature of this trial, it is reasonable to think that under "normal" conditions protection would last for 6 months.

As for the collars that were lost during the trial, the cause is most probably due to the very special conditions of the dogs' environment.

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
  - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. 6th to 90th day after application
  - Tested a.i. application rate: Not determinable
  - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Living animal
  - Formulation type (e.g. aerosol, granular): Treated collar
  - Application type (e.g. direct, surface, area): Surface
  - Timepoints at which corresponding control mortality is greater than 10%: Not reported

Conclusions

- Use of a Scalibur collar containing an unreported concentration of Deltamethrin, caused ≥90% reduction in flea numbers from the 6th to 90th day after application.
- Because of how the data were reported, precise 90% efficacy levels were not determinable.